

IN THE UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF OHIO (COLUMBUS)

Carolyn R. Carter
242 S. Hampton Rd.
Columbus, OH 43213,

Plaintiff,

V.

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604,
c/o CT Corporation System, S.A.
1300 E. 9th Street
Cleveland, OH 44114,

Medtronic Neuromodulation
7000 Central Avenue NE
Fridley, Minnesota 55432,

Medtronic Puerto Rico Operations Co.
Ceiba Norte Industrial Park Road 31, Km. 24
HM 4 Call Box 4070
Junco 00777-4070, Puerto Rico, and

Medtronic Logistics, LLC
710 Medtronic Parkway
Minneapolis, MN 55432-5604,

Defendants.

[illegible]

Case No.: 2:18-CV-724

Judge _____

Magistrate Judge _____

**JURY DEMAND ENDORSED
HEREON**

COMPLAINT

Now comes Plaintiff Carolyn R. Carter (“Mrs. Carter”), by and through her undersigned counsel, and for her *Complaint* against Defendants Medtronic, Inc. (“Medtronic”), Medtronic Neuromodulation, Medtronic Puerto Rico Operations Co., and Medtronic Logistics, LLC (collectively, the “Medtronic Defendants”) does hereby aver the following:

JURISDICTION, VENUE, STATUTE OF LIMITATIONS, AND STATUTE OF REPOSE

1. Mrs. Carter is a resident of Ohio.
2. Medtronic is a Minnesota corporation with its principal place of business in Minnesota who is chartered as a foreign entity to conduct business in Ohio with the Ohio Secretary of State under Entity Number 484718.
3. At all times, relevant hereto, Medtronic was involved in the design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or marketing and/or distribution and/or sale and/or promotion and/or was otherwise involved in the placing in the stream of commerce medical devices and a device specifically called the SynchroMed® II Programmable Implantable Infusion Pump System (hereinafter referred to as “SynchroMed® II Device”).¹
4. Medtronic Neuromodulation (“Medtronic Neuro”), a business unit of Medtronic, manufactures medical devices, including but not limited to, SynchroMed II implantable infusion pumps.
5. Medtronic Neuro was involved in the design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or marketing and/or distribution and/or sale and/or promotion and/or was otherwise involved in the placing in the stream of commerce medical devices and the SynchroMed® II Device.

¹ The terms “SynchroMed II Device” or “SynchroMed II pump” herein includes the intrathecal sutureless catheter.

6. The headquarters of Medtronic Neuro is located at 7000 Central Ave. NE, Minneapolis, MN 55432, and its manufacturing facility is located at 53rd Avenue, NE, Columbia Heights, MN 55421.

7. Medtronic Puerto Rico Operations Co. was and is a corporation or other business entity and a wholly owned subsidiary of Medtronic, with its principal place of business in Ceiba Norte Industrial Park Road 31, Km. 24, HM 4 Call Box 4070, Junco 00777-4070, Puerto Rico, and was involved in the design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce medical devices and the SynchroMed® II Device.

8. At all times relevant hereto, Medtronic Logistics, LLC, was and is a limited liability corporation or other business entity and wholly owned subsidiary of Medtronic, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432, and was involved in the design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce medical devices and the SynchroMed® II Device.

9. At all times, relevant to this action, the Medtronic Defendants were authorized to do business within Ohio, and manufactured, supplied, distributed, formulated, prescribed, marketed, and sold or otherwise placed into the stream of commerce the SynchroMed® II Device within Ohio.

10. Mrs. Carter suffers from chronic back pain.

11. Mrs. Carter treated with Dr. Bruce A. Massau, D.O. ("Dr. Massau") in Franklin County, Ohio for said chronic pain.

12. This litigation arises from multiple implantations of implantable infusion pumps manufactured by the Medtronic Defendants.

13. Mrs. Carter's injuries alleged herein proximately resulted from the negligent and/or reckless and/or other wrongful acts and omissions, and fraudulent representations of these defendants and/or each of them, all of which occurred within the jurisdiction of this Honorable Court.

14. This litigation is timely filed and is not barred by any applicable statute of limitation or repose.

15. This Honorable Court has jurisdiction over this ripe case and controversy pursuant to 28 U.S.C. §1332 because this is a civil action between citizens of different states and the amount in controversy exceeds the sum of \$75,000.00, exclusive of costs and interest.

16. Venue in this district is proper pursuant to 28 U.S.C. §1391(b) as a substantial part or omission occurred in this judicial district.

STATEMENT OF FACTS

17. Mrs. Carter alleges and incorporates herein each and every allegation set forth in the preceding paragraphs as though the same were fully rewritten herein.

18. Mrs. Carter is a sixty-five (65) year old woman who suffered serious injuries from a malfunctioning and defective SynchroMed® II Device from the Medtronic Defendants. This Pump 5 was designed, tested, manufactured, produced, processed, assembled, inspected,

distributed, marketed, labeled, promoted, packaged, advertised for sale, placed in the stream of commerce, and sold or otherwise provided to Mrs. Carter by the Medtronic Defendants.

19. Throughout the history of the manufacture of the SynchroMed® II Device, the U.S. Food & Drug Administration (FDA) has repeatedly notified the Medtronic Defendants that their manufacture of the SynchroMed® II Device failed to conform to manufacturing requirements enumerated in federal regulations and statutes. These federal violations caused the defects and malfunctions in Mrs. Carter's Pump 3 through Pump 5, which caused her injuries and damages alleged herein.

20. Throughout the history of the manufacture of the SynchroMed® II Device, the Medtronic Defendants has shown an indifference to federal manufacturing requirements. Further, the Medtronic Defendants, with full knowledge that they were manufacturing the SynchroMed® II Device in violation of law, nonetheless demonstrated a pattern of delayed responses or complete failures to respond to reported and known safety issues with the SynchroMed® II Device.

21. Because of the Medtronic Defendants' years-long pattern of indifference to regulatory authority, noncompliance with federal manufacturing requirements, and violations of federal law, the U.S. Department of Justice and the U.S. Department of Health and Human Services on April 27, 2015 filed a Complaint against the Medtronic Defendants requesting a Consent Decree for Permanent Injunction against the manufacture, distribution, and sale of the SynchroMed® II Device.

22. As a foreseeable, direct and proximate result of the Medtronic Defendants' conduct described herein, Mrs. Carter has suffered and will continue to suffer damages, including lost

wages and benefits, diminished wages and future earnings, mental anxiety and anguish, loss of self-esteem, and medical bills in amounts to be proven at trial.

The SynchroMed® II Device

23. The SynchroMed® II Device is a programmable drug infusion system implanted in the body for drug delivery. The SynchroMed® II Device includes an infusion pump connected to a thin, flexible catheter attached to the intrathecal space (spinal canal) of the patient, into which the SynchroMed® II Device delivers medication. The relevant SynchroMed® II Device, the Pump 5 further described below, was used to administer pain medication to Mrs. Carter.

24. The SynchroMed® II Device is a Class III medical device, approved by the FDA through the Pre-Market Approval (PMA) process in 1988. Since the initial approval under PMA 860004, the Medtronic Defendants sought FDA approval of at least one hundred ninety-one (191) supplements or changes to the originally-approved SynchroMed® II Device.

25. The pump of the SynchroMed® II Device is supplied in twenty (20) and forty (40) ml reservoir sizes, Models #8637-20 and 8637-40 respectively, and Pump 5 is approved solely for the following uses: a. the chronic epidural/intrathecal infusion of Infumorph (preservative-free morphine sulfate sterile solution) and Prialt® (preservative-free ziconotide sterile solution) for the management of pain; b. the chronic intrathecal infusion of Baclofen (Lioresal) for the management of severe spasticity; and c. the chronic intravascular infusion of floxuridine (FDUR) and methotrexate for the treatment of primary or metastatic cancer.

26. The entire SynchroMed® II Device is implanted and remains under the skin. A clinician measures a precise amount of medication and injects the medication into the pump's reservoir fill port. The medication passes through a reservoir valve and into the pump reservoir.

At normal body temperatures, pressurized gas, used as a propellant, is stored below the reservoir and it expands and exerts constant pressure on the reservoir. This pressure pushes the medication into the pump tubing. The battery-powered electronics and motor gears deliver a programmed dose of medication through the tubing out through a catheter port and into a catheter. Medication delivery then continues through the catheter tubing and into the intrathecal space of a patient.

27. The intrathecal catheters and sutureless revision kits of the SynchroMed® II Device are designed to connect the pump with the patient's intrathecal space. Each catheter has a pre-attached strain relief sleeve, a connector pin, and a sutureless pump connector that connects to the SynchroMed® II pump (SynchroMed® II Device and SynchroMed® II pump are used interchangeably herein throughout the mean the same mechanism).

28. In their marketing, the Medtronic Defendants represented the SynchroMed® II Device as "safe effective, reliable medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, including the controlled release of Morphine for the treatment of patients suffering from chronic and severe pain."

29. Medtronic Defendants marketed the SynchroMed® II Device directly to patients through conversations with Medtronic Defendants' employees or agents, patient testimonials, and colorful brochures with images of individuals smiling and pain medication patients riding motorcycles. the Medtronic Defendants' representations to patients include: a. "a safer way to receive pain medication"; b. "help you rejoin life so you can get back to the activities and people that make you happiest"; c. "allows you to 'Tame your Pain'"; d. "reduce your need for oral pain medications"; e. "provide peace of mind knowing that you've selected a drug delivery

system that was manufactured by Medtronic...”; f. “give reassurance because only Medtronic offers a programmable drug delivery system that is FDA approved for MRI scans...”; g. “increase your confidence when you consider that more than 150,000 people worldwide have used Medtronic drug delivery therapy to manage their chronic pain”; h. “drug delivery therapy from Medtronic is a *proven safe and effective therapy*”; i. “Medtronic drug delivery therapy has been tested, is shipped sterile, and is FDA approved”; and j. “more doctors trust Medtronic than any other company offering drug delivery therapy.”

FDA Pre-Market Approval (PMA) of the SynchroMed® II Device

30. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III medical devices are those that 1) support or sustain human life, 2) are of substantial importance in preventing impairment of human health, or 3) which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, these devices require a premarket approval (PMA) application under Section 515 of the Federal Food Drug and Cosmetic Act (FD&C Act) before they can be sold in the United States. As mentioned, the SynchroMed® II Device is a Class III medical device.

31. In a PMA application, the applicant is required to supply information to the FDA. The information required includes: a) device description, b) clinical safety trials, c) methods of its product testing, d) design of Pump 5 and specific manufacturing controls, e) outcome evaluation, and f) proposed labeling. The FDA does not conduct independent testing on a medical device in a PMA application. The FDA reviews the documentation provided to them by the PMA applicant and relies on the veracity of the company. The PMA applicant (in this

circumstance, the Medtronic Defendants) is solely responsible for submitting all truthful and necessary documentation to the FDA.

32. Once an application for PMA is approved, the holder, the Medtronic Defendants, must comply with any and all post approval requirements established by the FDA and federal regulations. The legal requirements include but are not limited to: post marketing monitoring, evaluating and reporting adverse events, and compliance with Current Good Manufacturing Practices (CGMPs). Regulations prohibit the PMA holder from selling an adulterated or misbranded product, and prohibit promoting a device for unapproved uses.

33. Federal regulations require a PMA applicant such as Medtronic Defendants to comply with the following requirements.

34. Federal regulations require the Medtronic Defendants to report individual adverse events within thirty (30) days after becoming aware of an adverse event or aware of a reportable death, serious injury or malfunction (21 C.F.R. §803.10(c)(1)).

35. Federal regulations require the Medtronic Defendants to report individual adverse events no later than five (5) work days after becoming aware of “a reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health...” (21 C.F.R. §803.10(c)(2)(i)).

36. Federal regulations require the Medtronic Defendants to establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured and that meets the requirement of this part. (21 C.F.R. §820.5).

37. Federal regulations impose on the Medtronic Defendants' management executives a responsibility to establish policies and objectives for, and commitment to quality. (21 C.F.R. §820.20).

38. Federal regulations require the Medtronic Defendants to have sufficient personnel with the necessary educational background, training, and experience to assure that all activities required by this part are correctly performed. (21 C.F.R. §820.25).

39. Federal regulations require the Medtronic Defendants to establish and maintain procedures for implementing corrective and preventive action, and document all activities under this section. (21 C.F.R. §820.100).

40. Federal regulations require the Medtronic Defendants to maintain complaint files, processed in a uniform and timely manner, oral complaints must be documents and must be evaluated to determine whether the complaint represents a reportable event under Medical Device Reporting. (21 C.F.R. §820.198).

41. Federal regulations require the Medtronic Defendants to establish and maintain procedures for identifying valid statistical techniques required for establishing controlling and verifying the acceptability of process capability and product characteristics. (21 C.F.R. §820.250).

42. Federal regulations prohibit the Medtronic Defendants from "misbranding" any device with a false or misleading label in any particular. (21 C.F.R. §820, *et al.*).

43. Federal regulations require the Medtronic Defendants to ensure that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are in conformity with applicable requirements, including but not limited to the Current Good Manufacturing Practice (CGMP) requirement of the Quality System regulations found at Title

21 Code of Federal Regulations Section 820, and if not so ensured, then such products are considered “*adulterated*.” (21 U.S.C. §351 (h) (emphasis added)).

44. Federal regulations prohibit the Medtronic Defendants from manufacturing, packaging, storing, labeling, distributing, advertising, or promoting in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for Pump 5. (21 C.F.R. §814.80).

**Violations of federal law resulting in Mrs. Carter’s defective and malfunctioning
SynchroMed® II Device**

45. The Medtronic Defendants, in their manufacture of the SynchroMed® II Device, violated federal law governing manufacture and quality control of PMA medical devices, which was discovered during a series of inspections by the FDA at Medtronic Defendants’ SynchroMed® II Device manufacturing and quality control plants in Minneapolis, Minnesota and Puerto Rico.

46. The inspections were followed by a series of Warning Letters to the Medtronic Defendants that identified federal manufacturing and quality control violations at the plants, ultimately leading to an April 27, 2015 *Complaint Requesting a Permanent Injunction* filed against the Medtronic Defendants by the U.S. Department of Justice and U.S. Department of Health and Human Services,² and a Court- Ordered FDA Consent Decree³ imposing a moratorium on the manufacture, sale, and distribution of the SynchroMed® II Device in violation of federal law.

² See the *Complaint for Permanent Injunction*, attached as Exhibit A.

³ See the *Consent Decree of Permanent Injunction*, attached as Exhibit B.

47. The Warning Letters, federal agency action, and FDA Consent Decree speak to the seriousness of the Medtronic Defendants' violations of federal law and general negligence in the manufacture of the SynchroMed® II Device.

48. In a 2006 Warning Letter, after an inspection of the Medtronic Defendants' manufacturing plant located at 800 53rd Avenue NE, Minneapolis, Minnesota, the FDA identified "Significant Deviations" from CGMPs committed by Medtronic Defendants while manufacturing their SynchroMed® II Devices" from CGMPs committed by Medtronic Defendants while manufacturing their SynchroMed® II Devices, including that which was implanted in Mrs. Carter's body. Given these "significant deviations," the SynchroMed® II Devices were found to be "**adulterated.**" These "significant deviations" include, but are not limited to, the following: a. Failure to control production processes to ensure that a device conforms to its specification. (21 C.F.R. §820.70(a)); b. Failure to implement corrective and preventive action procedures addressing the investigation of the cause of nonconformities. (21 C.F.R. §820.100(a)(2)); c. Failure to implement changes in methods and procedures needed to correct and prevent identified quality problems. (21 C.F.R. §820.100(a)(5)); d. Failure to identify all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems. (21 C.F.R. §820.100(a)(3)); and e. Failure to implement procedures to ensure that device history records for each batch, or unit are maintained to demonstrate that Pump 5 is manufactured in accordance with regulations. (21 C.F.R. §820.184).

49. The 2006 FDA Warning Letter continued: *"The specific violations noted in this letter and the Form FDA-483... may be symptomatic of serious underlying problems in your firm's manufacturing quality assurance systems."*⁴

50. The FDA inspected the same Minneapolis Medtronic Defendants facility less than a year later, and on July 3, 2007 issued *another* Warning Letter concerning the SynchroMed® II Device. The FDA again warned the Medtronic Defendants that their devices manufactured at the Minneapolis facility were *"adulterated"* and *"misbranded."* A partial list of the violations the FDA found during the 2007 inspection includes: a. the Medtronic Defendants failed to implement complaint handling procedures to ensure that all complaints are evaluated to determine whether the complaint represents an event that must be filed as a Medical Device Report (MDR); b. the Medtronic Defendants failed to enter several medical and/or scientific literature articles discussing adverse events relating to devices the plant manufactured in the reporting system and failed to evaluate whether the adverse event related articles were required to be reported to the FDA under 21 C.F.R. §803.50; and c. the Medtronic Defendants failed to submit MDR reports within thirty (30) days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury (21 C.F.R. §803.50(a)(1)).

51. In that July 3, 2007 Letter, the FDA warned the Medtronic Defendants: "[y]our firm has several procedures for Medical Device Reporting and Adverse Drug Experience Reporting. These procedures, in turn reference several other procedures. You firm's current problems

⁴ See the August 29, 2006 FDA Warning Letter and Form FDA 483, dated January 24, 2007, attached collectively as Exhibit C.

regarding MDR reporting, as discussed above in this Warning letter, may be exacerbated by the complexity of your procedures and might have contributed to your firm's deviations from the regulations regarding MDR reporting."⁵

52. The FDA inspection also revealed several ongoing violations at Medtronic Defendants' Minneapolis Plant's Quality System that were noted in a Form 483, stating "[t]he specific violations noted in this letter and Form FDA 483 may be symptomatic of serious underlying problems in your firm's manufacturing and Quality Assurance systems." Specifically, the FDA warned that Medtronic Defendants: a. that Medtronic Defendants failed to achieve consistent compliance in areas such as design controls. (21 C.F.R. §820.30); and b. failed to achieve consistent compliance in Corrective and Preventative Action (CAPA). (21 C.F.R. §820.100).⁶

53. On June 1, 2009, the FDA issued a "Warning Letter" to the Medtronic Defendants concerning their manufacturing facility in Juncos, Puerto Rico, detailing multiple violations of "Current Good Manufacturing Practice (CGMP) requirement of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.) part 820" based on inspections conducted in late 2008. Based upon those violations, the FDA determined that Medtronic Defendants' SynchroMed® II Devices were "*adulterated*" within the meaning of 831(h) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. *et seq.* "in that the methods used in, or the facilities or controls used for, their manufacture, packing, sorting, or installation are not in

⁵ See the July 3, 2007 FDA Warning Letter, attached as Exhibit D.

⁶ *Id.*

conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation found at Title 21 Code of Federal Regulations (C.F.R.) Part 820.”⁷

54. The 2009 FDA Warning Letter concerning the Puerto Rico manufacturing plant specifically cited the Medtronic Defendants for the following with regard to the SynchroMed® II Device: a. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, which shall include monitoring and control of process parameters and component and device characteristics during production; b. Failure to establish and maintain procedures for implementing corrective and preventive actions that include identifying the actions needed to correct and prevent recurrence of non-conforming product and other quality problems as required by 21 C.F.R. §820.100(a); c. Failure to establish and maintain procedures that ensure Pump 5 History Records (DHRs) for each batch, lot or unit are maintained to demonstrate that Pump 5 is manufactured in accordance with the DHR as required by 21 C.F.R. §820.184; d. Failure to review, evaluate and investigate complaint involving the possible failure of a device, labeling or packaging to meet any of its specifications as required by 21 C.F.R. §820.198(c); e. Failure to report to FDA no later than thirty (30) calendar days after the day that the Medtronic Defendants received or otherwise became aware of information from any source, that reasonably suggests that a device Medtronic Defendants marketed: 1) may have caused or contributed to a death or serious injury; or 2) has malfunctioned and this device or a similar device that Medtronic Defendants marketed would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as

⁷ See the June 1, 2009 FDA Warning Letter, attached as Exhibit E.

required by 21 C.F.R. §803.50(a); f. Failure to have a person who is qualified to make a medical judgment reasonably conclude that a device did not cause or contribute to a death of serious injury, or that a malfunction would not likely to cause or contribute to a death or serious injury if it were to recur, as required by 21 C.F.R. §803(c)(2); and g. Failure to ensure that persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomechanical engineers under 21 C.F.R. §803.20(c)(2): “[O]ur investigators determine that a product reporting specialist was making decisions about MDR reportability for the Medtronic Defendants SynchroMed® II Implantable Pump Infusion System. The training record for this particular employee showed that this person only had a high school diploma with some additional in-house training.”⁸

55. At the time of inspection, the FDA informed the Medtronic Defendants of the following manufacturing defects in the SynchroMed® II Device: a. Pumps manufactured without propellant. The FDA noted that while Medtronic Defendants *identified* this problem in May of 2006, and initiated a corrective and preventative action (CAPA) investigation in January 2007, the Medtronic Defendants did not voluntarily recall the thirteen thousand five hundred fifteen (13,515) devices affected by this defect until May 2008, a *full two (2) years after the defect was identified*. b. Pumps did not show evidence of perforated septum; c. Pumps were missing a safety mechanism that served to assure that pumps are never overfilled; and d. A *critical step was left out of the manufacturing process*, which is the calculation of drug reservoir levels and drug dispensing rates. Despite numerous complaints that the Medtronic Defendants received

⁸ Id.

regarding accuracy rates, the Medtronic Defendants failed to conduct any type of investigation into this problem.

56. The FDA determined that the SynchroMed® II Device was “*misbranded*” by virtue of the cited violation involving the failure or refusal to furnish material or information required under the statute and regulations relating to information that Pump 5s may have either caused or contributed to death or serious bodily injury, or malfunctions in such a way that if it were to recur would be likely to cause or contribute to a death or serious injury.

57. Additionally, while the FDA observed generally that the adequacy of the Medtronic Defendants’ responses could not be determined at the time, the FDA noted “the adequacy of your corrective and preventative measures will be determined during the next inspection.” It specifically noted that Medtronic Defendants’ response to the violation related to the “failure to establish and maintain procedures for implementing Corrective and Preventive Action (CAPA) procedures at [the Puerto Rico facility] will be conducted by July 31, 2009.”⁹

58. In 2012, the Medtronic Defendants’ Minneapolis manufacturing plant was again inspected by the FDA. As a result of that inspection, the FDA issued a Warning Letter dated July 17, 2012 identifying the Medtronic Defendants’ specific violations of federal regulations in the manufacture of SynchroMed® II Devices including violations of CGMPs and Quality Systems requirements. The FDA informed the Medtronic Defendants that the SynchroMed® II Devices were “*adulterated*.”

⁹ Id.

59. The FDA cited the Medtronic Defendants for incomplete complaint data and incorrect coding decision. The FDA stated this violation “may have compromised Medtronic’s ability to detect and investigate [safety] signals.”¹⁰

60. From February 14, 2013 through April 3, 2013, the FDA again inspected the Medtronic Defendants’ Neuromodulation manufacturing plant in Minneapolis. In April 2013, based on its inspection, the FDA informed the Medtronic Defendants that the plant failed to manufacture devices that adequately conform to specifications and instead manufactured devices that were not adequately controlled. Specifically, the Medtronic Defendants failed to establish procedures for corrective and preventative action for problems including: a. “Feed through shorting” resulting in motor stalls, whereby at least two hundred ninety-eight (298) serious adverse events have resulted from this defect; b. Based upon a reported problem with their device, the Medtronic Defendants failed to implement a recommendation from its Risk Evaluation Board and delayed any action taken. Since the decision to delay the action, at least thirty-seven (37) serious adverse events have been possibly related to the problem; and c. the Medtronic Defendants detected signals showing a problem with catheter occlusion, but failed to update a Health Hazard Assessment for this defect since 2008, with over three hundred (300) complaints occurring since that time.¹¹

61. Further, the FDA notified the Medtronic Defendants of the following: Regulatory approval was received for Supplement 136 to PMA P860004 on December 15, 2011 to change the

¹⁰ See the July 17, 2012 FDA Warning Letter, attached as Exhibit F.

¹¹ See the FDA Form 483, Inspection Observations, Dated Feb. 14, 2013 – April 3, 2013, attached as Exhibit G.

design of SC Catheter models 8709 SC, 8731 SC, 8596 SC, and Revision Kit model 8578 to mitigate a known field issue associated with CAPA 1507-SC Catheter Occlusion. This design change was implemented via ECO 12-00985, date March 6, 2012, and the new revisions of Catheter models were released to the field in September 2012. However, the previous SC catheter models which do not conform to the current design have continued to be distributed and have been attributed to 60 complaints of catheter occlusion since September 2012.¹²

SynchroMed® II Device recalls initiated by the FDA

62. Since 2008, the FDA has issued **NINETEEN (19)** Class I Recall Actions for the SynchroMed® II Device. A recall is an action taken to address a problem with a medical device that violates federal law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

63. A Class I recall is the most serious recall category issued when there is a probability that the use of the product could cause serious health consequences or death. Any drug or medical device that has been the subject of a Class I recall can be deadly or cause serious life-long injury.

64. Up to December 13, 2012, The Class I and Class II recalls issued for the SynchroMed® II Device include, but are not limited to: a. Formation of inflammatory masses near the tip of the intrathecal catheters (Class I, March 22, 2008); b. Pumps manufactured without propellant (Class II, September 3, 2008); c. Battery failure (Class II, September 29, 2009); d. Inadequate instruction for filling/refilling of pumps causing injection of all or some of the

¹² Id.

prescribed drug into the patient's subcutaneous tissue (Class I, August 29, 2011); e. Reduced battery performance leading to sudden loss of therapy (Class I, August 29, 2011); f. Software failure resulting in incorrectly displayed "scheduled to replace the pump by" date (Class II, March 30, 2012); and g. Use of unapproved (off-label) drugs in the pumps leading to permanent motor stall and cessation of infusion (December 13, 2012).

65. On June 3, 2013, the FDA issued two (2) Class I recalls related to the Medtronic Defendants SynchroMed® II Implantable Infusion Pump System. a. The first 2013 recall covers all of the SynchroMed® II pumps implanted worldwide manufactured from May 1998 through June 2013 and distributed from April 1999 through June 2013. In the letter, the FDA warned that the following would happen with the defective pumps: i. Unintended delivery of drugs during the priming bolus procedure can result in drug under-delivery and over-delivery, leading to respiratory depression, coma or death, and ii. Potential for electrical shorting, internal to the SynchroMed® II infusion pump, leading to a loss of or reduction in therapy, resulting in serious adverse health consequences including death. At the time of the 2013 recalls, there were two hundred sixty-one thousand, one hundred nine (261,109) SynchroMed® II Implantable Infusion Pumps System implanted worldwide. b. The second 2013 recall affects all Sutureless Connector Intrathecal Catheters in the SynchroMed® II Device, Models #8709SC, 8731SC, and Sutureless Revision Kits, Models #8596SC, and 8578 with a "use by" date of August 25, 2014. In the recall, the FDA noted the reasons for the recall: i. "The sutureless Connector Intrathecal Catheter connector has been redesigned to reduce the potential for occlusion, which is the blockage or stoppage of drug flow due to misalignment at the point where the catheter connects to an implantable pump. The Medtronic Defendants are removing all unused products that were

manufactured with the previous design. The Medtronic Defendants recommends the previous design of Sutureless connector Intrathecal Catheter Products no longer be used due to greater potential for misalignment and subsequent occlusion.” ii. “This product may cause serious adverse health consequences, including drug under dose, loss of symptom relief, drug withdrawal symptoms caused by the lack of drug delivery to the intrathecal space, and/or death.”

The Complaint for Permanent Injunction against the Medtronic Defendants

66. On April 27, 2015, the United States Department of Justice and United States Department of Health and Human Services filed suit against the Medtronic Defendants in the case styled USA v. Medtronic, Inc., et al., United States District Court for the District of Minnesota, Case No.: 15-2168 (“FDA Suit”) for a permanent injunction against Medtronic, S. Omar Ishrak, and Thomas M. Tefft with respect to their manufacture of the SynchroMed® II Device.¹³

67. Said Complaint alleges that Medtronic Defendants, S. Omar Ishrak, and Thomas M. Tefft “are well aware that their practices violate the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants’ compliance with the Act.”

68. In addition to the cited Warning Letters, the said Complaint alleges that representatives of Medtronic Defendants attended a meeting with FDA’s Center for Devices and Radiological Health and Minneapolis District Office on January 31, 2013. At this meeting,

¹³ See the *Complaint for Permanent Injunction* in the FDA Suit attached and fully incorporated herein at Exhibit A.

“Defendants stated that they were aware of the violations at their facilities and were taking steps to correct them.”

69. The Complaint further alleges Medtronic Defendants made promises to correct their violations in written responses to each inspection; however, the Complaint alleged that none of the responses contained adequate evidence that Medtronic Defendants corrected their deviations.

70. The United States Attorney stated in the Complaint that, *“[b]ased upon Defendants’ conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§331(a) and (k) [introducing into interstate commerce any article of device that is **adulterated**, or causing any article of device to become **adulterated** within the meaning of 21 U.S.C. §351 (h) while such devices are held for sale after shipment in interstate commerce].”*

71. Said Complaint requested a permanent injunction to restrain Medtronic Defendants, in their manufacture of the SynchroMed® II Device, from their continued violation of federal regulations, and, *“That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly and indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) SynchroMed II implantable infusion pumps at or from its Medtronic Defendants’ Neuromodulation facilities, unless and until Medtronic Defendants’ methods, facilities, and controls used to manufacture, process, pack, label, hold and distribute the SynchroMed II implantable infusion pumps are established, operated, and administered in compliance with 21 USC 360j(f)(1) and the Quality*

System regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA.¹⁴

72. In the FDA Suit, the FDA claimed that Medtronic Defendants violated FDCA, Section 331(a) “by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. §321(h), that are adulterated within the meaning of the FDCA, 21 U.S.C. §351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice requirements prescribed at 21 C.F.R. Part 820.”

73. In the FDA Suit, the FDA claimed that Medtronic Defendants violated the FDCA, “21 U.S.C. §331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. §351(h)” as described in paragraph above, “while such devices are held for sale after shipment in interstate commerce.”

74. The Medtronic Defendants manufacture and distribute via interstate commerce various articles of devices, as defined by 21 U.S.C. §321(h), including, but not limited to, SynchroMed II implantable infusion pumps and the Medtronic Defendants’ Ascenda Intrathecal Catheter.

75. The Medtronic Defendants’ products are devices, within the meaning of 21 U.S.C. §321(h), in that they are intended to affect the structure or any function of the body of man.

¹⁴ Id.

76. The Medtronic Defendants' devices must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure the safety and effectiveness of the Medtronic Defendants' devices under 21 U.S.C. §360j(f).

77. The statutory good manufacturing practice requirement is set out in the quality system ("QS") regulation for devices, 21 C.F.R. Part 820.

78. A device that has been manufactured, packed, stored, or installed in violation of this requirement in 21 C.F.R. Part 820 is deemed to be adulterated under 21 U.S.C. §351(h).

79. The FDA claimed in the FDA Suit that Medtronic Defendants' medical devices were adulterated under 21 U.S.C. §351(h).

80. The introduction or delivery for introduction into interstate commerce of an adulterated article of device is a violation of the FDCA, 21 U.S.C. §331(a).

81. The adulteration of a device while it is held for sale after shipment in interstate commerce constitutes a violation of the FDCA, 21 U.S.C. §331(k).

82. Based on the Medtronic Defendants' actions and omissions noted in the FDA's aforementioned inspections of Medtronic Defendants, the FDA alleged in the FDA Suit that, unless restrained by an order of court therein that Medtronic Defendants would continue to violate 21 U.S.C. §§331(a) and (k).

83. On April 27, 2015, in the FDA Suit, United States District Court Judge Joan N. Erickson signed a *Consent Decree of Permanent Injunction* ("FDA Consent Decree") against the Medtronic Defendants preventing the manufacture and distribution of the Medtronic

Defendants' SynchroMed® Implantable Infusion Pump systems in violation of the terms of the FDA Consent Decree.¹⁵

84. Under the FDA Consent Decree, the Medtronic Defendants are “permanently restrained and enjoined, pursuant to 21 U.S.C. §332(a), from directly or indirectly designing, manufacturing, processing, packing, labeling, holding, storing, and distributing, importing into or exporting from the United States of America, at or from any Medtronic Defendants Neuromodulation facilities, any model of, or components or accessories for, its SynchroMed devices.” Under the FDA Consent Decree, the permanent injunction would be lifted only in the event that Medtronic Defendants complies with a series of enumerated requirements to ensure that it would cease violating federal law in the production of its SynchroMed® II Device.

85. The FDA Consent Decree cites violations of the quality system regulation for medical devices, which requires manufacturers like Medtronic Defendants to have processes in place to assure that the design, manufacture, distribution, instruction, and warning of a medical device allows for its safe use.

86. The FDA Consent Decree requires Medtronic Defendants to stop manufacturing, designing and distributing SynchroMed II implantable infusion pumps except in very limited cases, such as when a physician determines that the SynchroMed II implantable infusion pump is medically necessary for a patient's treatment.

87. The FDA Consent Decree also requires Medtronic Defendants to retain a third-party expert to help develop and submit plans to the FDA to correct violations.

¹⁵ See a true and accurate copy of this FDA Consent Decree attached hereto and incorporated fully herein at Exhibit B.

88. The FDA Consent Decree will remain in effect until the FDA has determined that Medtronic Defendants has met all the provisions listed in the FDA Consent Decree.

89. Under the FDA Consent Decree, once Medtronic Defendants receives permission from the FDA to resume the design, manufacture, distribution, instruction, and warnings regarding these products, then Medtronic Defendants must continue to submit audit reports so the FDA can verify Medtronic Defendants' compliance.

90. In addition to these audits, the FDA Consent Decree provides that the FDA will monitor Medtronic Defendants' activities through the FDA's own inspections.

91. Upon information and belief, the Medtronic Defendants continue to produce, distribute, and sell their SynchroMed® II Device in violation of the FDA Consent Decree.

Mrs. Carter's Medical History

92. Around May 18, 1998, the aforesaid Dr. Massau implanted in Mrs. Carter a SynchroMed implantable infusion pump, Model 8617L18 Serial Number NDA005983R, and an Intrathecal Catheter from Medtronic for her chronic pain ("Pump 1") due to failed back surgery syndrome, M96.1. The Pump 1 implant occurred in Franklin County, Ohio at Doctors Hospital.

93. Around April 13, 2001, Dr. Massau explanted Pump 1 with SynchroMed EL pump and accompanying catheter, Model 8627L18 Serial Number NGH010083R ("Pump 2"). The explant of Pump 1 and the simultaneous implant of Pump 2 occurred in Franklin County, Ohio at The Ohio State University, East Hospital.

94. Around August 18, 2004, Dr. Massau explanted Pump 2 with a SynchroMed II model and accompanying catheter from the Medtronic Defendants, Model 8637-40 Serial Number

NGV003487N ("Pump 3"), in a procedure conducted in Franklin County, Ohio at The Ohio State University, East Hospital.

95. Around September 28, 2005, Dr. Massau explanted Pump 3 and implanted a new SynchroMed II pump and accompanying catheter, Model 8637-40 Serial Number NGV012655N ("Pump 4") in a procedure conducted in Franklin County, Ohio at The Ohio State University, East Hospital.

96. Dr. Massau diagnosed the explant of Pump 3 as premature due to Pump 3's failure.

97. Around April 25, 2012, Dr. Massau explanted Pump 4 and implanted a new SynchroMed II pump and accompanying catheter, Model 8637-40 Serial Number NGV458028H ("Pump 5") in a procedure conducted in Franklin County, Ohio at the OhioHealth Grant Medical Center.

98. Dr. Massau diagnosed the explant of Pump 4 as premature due to Pump 4's failure.

99. On November 25, 2015, Dr. Massau diagnosed Pump 5 as experiencing a motor stall.

100. On January 27, 2016, Dr. Massau diagnosed Pump 5 as experiencing a motor stall.

101. On February 21, 2016, Dr. Massau diagnosed Pump 5 as experiencing a motor stall.

102. Before July 27, 2016, Dr. Massau conducted a rotor dye study on Pump 5 to confirm a "complete stop of her rotors."

103. Dr. Massau explanted Pump 5 on July 27, 2016 in a procedure conducted in Franklin County, Ohio due to a premature failure of Pump 5 with a stalled rotor/stalled motor.

104. Dr. Massau diagnosed the premature failure of Pump 5 due to a stalled rotor/stalled motor.

105. Dr. Massau diagnosed Mrs. Carter as experiencing signs of withdrawal given the lack of medicine delivery by the stalled rotor/stalled motor in Pump 5.

106. On August 9, 2017, the Medtronic Defendants recalled Medtronic SynchroMed II Model 8637 supplied in 20 mL and 40 mL reservoir size and a catheter, Recall Event ID 78609, to address the stalled rotor/motor stall.

107. Pump 5 implanted into Mrs. Carter was produced by the Medtronic Defendants during the time period of these 2013 recalls by the FDA.

108. Pump 5 implanted into Mrs. Carter was produced by the Medtronic Defendants and experienced a rotor stall/motor stall as described in the Medtronic Defendants' August 9, 2017 recall.

109. Dr. Massau persuaded Mrs. Carter to have Pump 3 through Pump 5 implanted in her abdomen to consistently administer pain medication into the intrathecal space of her spine.

110. Pump 3 through Pump 5 implanted into Mrs. Carter was intended to deliver a programmed amount of pain medication into her spine, reducing or eliminating the need for oral medications pursuant to the Medtronic Defendant's warranties and representations on the safety and effectiveness of the SynchroMed® II Device.

111. Upon information and belief, Pump 3 through Pump 5 which Mrs. Carter received was designed, manufactured, and distributed by the Medtronic Defendants.

112. Pump 5 which Mrs. Carter received in 2012 was manufactured and distributed concurrently during the period of the FDA's abovementioned Inspection of the Medtronic Defendants.

113. Upon information and belief, Pump 5 which Mrs. Carter received in 2012 was subject to and part of the Medtronic Defendants' violations of the FDCA.

114. Pump 5 which Mrs. Carter received in 2012 was affected by Medtronic Defendants' violations of the FDCA.

115. The FDA and/or the Medtronic Defendants later recalled the Medtronic Defendants' Ascenda Intrathecal Catheter, Model 8780 in 2014 for a nonconforming material/component.

116. The Medtronic Defendants' Ascenda Intrathecal Catheter, Model 8780 recall occurred due to a component of the said catheter not meeting specification criteria and permitting the unintentional disconnection from the SynchroMed II implantable infusion pumps.

117. Upon information and belief, the FDA/s and/or the Medtronic Defendants' recall of the Medtronic Defendants' Ascenda Intrathecal Catheter, Model 8780 included catheters distributed in Ohio.

118. The FDA and/or the Medtronic Defendants also recalled the SynchroMed II implantable infusion pumps in June of 2013 due to unintended delivery of drugs that contributed to drug over-dosage, under-dosage, and drug withdrawals.

119. Mrs. Carter received her Pump 5 just before the June of 2013 recall SynchroMed II implantable infusion pumps.

120. Mrs. Carter's Pump 3 through Pump 5 suffered from the drug over-dosage, under-dosage, and drug withdrawals as the SynchroMed II implantable infusion pumps recalled in June of 2013.

121. The FDA and/or the Medtronic Defendants also later recalled the SynchroMed II implantable infusion pumps in June of 2013 due to potential for electrical shortages resulting in drug over-dosage, under-dosage, and drug withdrawals.

122. The FDA and/or the Medtronic Defendants also later recalled the SynchroMed II implantable infusion pumps in February of 2014 due to over infusion of drugs that could result in drug over-dosage, under-dosage, and drug withdrawals.

123. The FDA and/or the Medtronic Defendants also later recalled the SynchroMed II implantable infusion pumps in April of 2015 due to audible alarm malfunctions.

124. Upon information and belief, the said recalls of the SynchroMed II implantable infusion pumps included pumps distributed in Ohio.

125. Upon information and belief, in October of 2016, the FDA/ and/or the Medtronic Defendants recalled the Pump 5 in follow up to the June of 2013 recall due to unintended delivery of drugs during the priming bolus function that contributed to drug over-dosage, under-dosage, and drug withdrawals with a software update.

126. Medtronic Defendants reports that pump system component failures leading to pump stall, or dosing/programming errors may result in clinically significant over-dosage and under-dosage.

127. Medtronic Defendants reports that pump system component failures can lead to acute massive overdose which may result in coma and may be life threatening.

128. As a result of the aforementioned defects and malfunctions, Mrs. Carter's defective Pump 5 failed to consistently deliver the prescribed medication as programmed.

129. These aforementioned defects and malfunctions resulted in failure to consistently deliver the programmed amount of pain medication into Mrs. Carter's spine, and thereby reducing or eliminating the need for oral medications pursuant to the Medtronic Defendant's warranties and representations on the safety and effectiveness of the SynchroMed® II Device, and thereby caused severe damage and injury to Mrs. Carter.

130. Mrs. Carter's defective and malfunctioning Pump 3 through Pump 5 necessitated removal surgeries. The removal of the defective device and replacement of a new device is a serious, invasive, and dangerous procedure.

131. Dr. Massau explanted Pump 3 through Pump 4 and returned the same to the Medtronic Defendants.

132. Mrs. Carter did not consent to the return of Pump 3 through Pump 4 to the Medtronic Defendants.

133. Mrs. Carter received no follow up from the Medtronic Defendants on the cause of failure for Pump 3 through Pump 5.

134. The Medtronic Defendants know the cause of failure in Pump 3 through Pump 5.

135. Mrs. Carter obtained the explanted Pump 5 from Dr. Massau and retains the same to the present date.

136. Dr. Massau, as a medical authority, informed Mrs. Carter that her bodily injury was related to Pump 3 through Pump 5.

137. During the time Mrs. Carter was under the treatment of Pump 3 through Pump 5 Mrs. Carter experienced unmitigated chronic pain, intermittent under-dosage, intermittent over-dosage, and intermittent drug withdrawal pains consistent with the FDA's findings of manufacturing defects in the FDA Suit.

138. Upon information and belief, the damage to Mrs. Carter's person from Pump 3 through Pump 5 is permanent and disfiguring.

COUNT ONE (1): MANUFACTURING DEFECT PER RC §§2307.71, ET SEQ.

139. Mrs. Carter alleges and incorporates herein each and every allegation set forth in the preceding paragraphs as though the same were fully rewritten herein.

140. Mrs. Carter herein asserts claims under Ohio law that parallel Medtronic Defendants' duties under federal law governing the manufacture of Mrs. Carter's Pump 3 through Pump 5.

141. Mrs. Carter's state law claims are based upon and arise from Medtronic Defendants' violations of and deviations from federal requirements in the manufacture of Mrs. Carter's Pump 3 through Pump 5.

142. The Medtronic Defendants, and each of them, are medical device companies engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise placing into the stream of commerce various medical devices intended for human use, as set forth herein, including the SynchroMed® II Device.

143. At all times relevant hereto, the Medtronic Defendants, and each of them, held themselves out as knowledgeable and possessing the requisite skill peculiar to the research

and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale of such product(s).

144. Medtronic Defendants manufactured, distributed, and sold Mrs. Carter's Pump 3 through Pump 5. At all times relevant hereto, Mrs. Carter used her SynchroMed® II Device for its intended purpose, which is intrathecal delivery of opioid medication for pain.

145. At all times relevant hereto, the Medtronic Defendants had a duty under federal law to manufacture Mrs. Carter's Pump 3 through Pump 5 in compliance with specifications imposed during the Pre-Market Approval for Pump 5, and in compliance with Post Approval federal regulations, including but not limited to those set out in 21 C.F.R. §801, et seq., 21 C.F.R. §803, et seq., 21 C.F.R. §814, et seq., 21 C.F.R. §806, et seq., 21 C.F.R. §820, et seq., and 21 U.S.C. §§351-52. Such regulations are promulgated to ensure that a manufactured device is free from defects.

146. At all times relevant hereto, the Medtronic Defendants had a duty under Ohio law to use reasonable care in the manufacture of their products, which includes a duty to manufacture Mrs. Carter's Pump 3 through Pump 5 in compliance with Medtronic Defendants' own specifications, a duty to prevent non-conforming devices from entering into the stream of commerce, and a duty to comply with safety regulations applicable to the manufacture of Pump 5. Such duties are parallel to those imposed under federal law and are expressly excepted from preemption under 21 C.F.R. §808.1(d)(2), according to which "state or local requirements that are equal to, or substantially identical to, requirements imposed by or under the [MDA]" are not preempted.

147. Medtronic Defendants breached their duties under Ohio law to use reasonable care in that they failed to ensure that Mrs. Carter's Pump 3 through Pump 5 complied with their own specifications and applicable safety regulations, including federal manufacturing requirements imposed by Pump 3 through Pump 5's Pre-Market Approval (PMA) requirements and Post Approval Regulations, and failed to test and inspect Mrs. Carter's Pump 3 through Pump 5 before placing them into the stream of commerce and making them available for sale to Mrs. Carter.

148. As a result of the Medtronic Defendants' violations of federal statutory and regulatory standard of care and device specific regulations, the SynchroMed® II Device implanted in Mrs. Carter's abdomen failed and required revision and removal surgeries.

149. At the time the SynchroMed® II Device implanted into Mrs. Carter's abdomen left the control of Medtronic Defendants, it was unreasonably dangerous due to the Medtronic Defendants' violations of the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated pursuant to it in one or more of the following ways: a. The SynchroMed® II Device was introduced or delivered for introduction into interstate commerce as *adulterated* in violation of 21 U.S.C. §§331, 351(h) and 21 C.F.R. Part 820; b. The SynchroMed® II Device was *adulterated* in interstate commerce in violation of 21 U.S.C. §§331, 351 (h) and 21 C.F.R. Part 820; c. The SynchroMed® II Device was received in interstate commerce *adulterated* and was delivered for pay or otherwise, in violation of 21 U.S.C. §§331, 351(h) and 21 C.F.R. Part 820; and d. The SynchroMed® II Device implanted in Mrs. Carter was *adulterated* because it was manufactured in deviation from the manufacturing specifications approved by the FDA in

Medtronic Defendants' PMA application in violation of the Federal Food, Drug, and Cosmetic Act.

150. At all times relevant hereto, federal law required Medtronic Defendants to manufacture the SynchroMed® II Device in compliance with federal specifications and requirements imposed through the PMA process for Pump 5, and in compliance with post-approval federal regulations, including but not limited to those set out in 21 C.F.R. §801, *et seq.*, 21 C.F.R. 803, *et seq.*, 21 C.F.R. §814, *et seq.*, 21 C.F.R. §806, *et seq.*, 21 C.F.R. §820, *et seq.*, and 21 U.S.C. §§351-352. Such regulations are promulgated to ensure a manufactured device is free from a defective condition unreasonably dangerous to the consumer.

151. Mrs. Carter suffered injury due to her non-conforming, adulterated, and defective Pump 3 through Pump 5.

152. As a result of the Medtronic Defendants' failure to use reasonable care in complying with federal law in the manufacture of Mrs. Carter's Pump 3 through Pump 5, Mrs. Carter's Pump 3 through Pump 5 were manufactured out of specification, were non-conforming, adulterated, and had the propensity for failure and malfunction and did fail and malfunction.

153. As a foreseeable, direct and proximate result of the Medtronic Defendants' negligence in manufacturing Mrs. Carter's Pump 3 through Pump 5, Mrs. Carter experienced severe pain and suffering which continues through present day and will continue into the future, a surgery to completely explant her defective SynchroMed® II Device, extensive hospitalization and medical procedures, and other damages compensable by law.

154. With their aforesaid actions, inactions, and federal law violations, the Medtronic Defendants manifested a flagrant disregard of the safety Mrs. Carter, who might be harmed by Pump 3 through Pump 5.

155. The Medtronic Defendants damaged Mrs. Carter including medical bills, lost income, permanent disfigurement, pain and suffering, and loss of consortium in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00), as will be more fully proven in the trial on the merits herein.

156. Mrs. Carter reserves the right to amend her pleadings herein or to join additional parties.

COUNT TWO (2): FAILURE TO WARN PER RC §§2307.71, ET SEQ.

157. Mrs. Carter alleges and incorporates herein each and every allegation set forth in the preceding paragraphs as though the same were fully rewritten herein.

158. Mrs. Carter herein asserts claims under Ohio law that parallel Medtronic Defendants' duties under federal law governing Mrs. Carter's Pump 3 through Pump 5. Mrs. Carter's state law claims are based upon and arise from Medtronic Defendants' violation of and deviation from federal regulations regarding Mrs. Carter's Pump 3 through Pump 5 as set forth herein.

159. Medtronic Defendants are medical device entities engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise placing into the stream of commerce various medical devices intended for human use, including the SynchroMed® II Device, which is a surgically implanted device that delivers medication into

the intrathecal space of patients for the treatment of chronic pain, and as an alternative to oral pain medication.

160. At all times relevant hereto, the Medtronic Defendants had a continuing duty under federal law and under Ohio law to monitor the SynchroMed® II Device placed into the stream of commerce, to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which Medtronic Defendants became aware, and that are or may be attributable to the product. (FD&C Act, Medical Device Reporting Title 21, Code of Federal Regulations (C.F.R.), Part 803)) "[R]equires manufacturers, distributors, and initial distributors of medical devices to establish, maintain a record of and report the result to FDA certain adverse events that they receive from any source, and to establish and maintain reports."

161. At all times relevant hereto, under Ohio law, the Medtronic Defendants had a duty to disclose to users and purchasers, including the FDA, of potentially dangerous risks involved in their product's use. Such duty imposes an obligation on the Medtronic Defendants to timely inform the FDA when Medtronic Defendants learned of the propensity for defects.

162. The Medtronic Defendants breached their duty under federal and Ohio law, in that it: a. Failed to report known problems with Devices;¹⁶ b. Failure to report consumer generated adverse events; c. Failed to report under 21 CFR 803, a "malfunction" event for an adverse event;¹⁷ and d. Failed to submit FDA-mandated Medical Device Reports (MDRs) within

¹⁶ See Exhibit D.

¹⁷ Id.

30 days of becoming aware that the SynchroMed® II Device caused or contributed to a death or serious injury, under 21 C.F.R. §803.50(a)(1), thereby resulting in Pump 5s being “misbranded.”¹⁸

163. The Medtronic Defendants knew at all times before Mrs. Carter was implanted with her SynchroMed® II Device that her Pump 3 through Pump 5 were defective in that they would not deliver the programmed rate of medication, yet the Medtronic Defendants failed to timely inform the FDA of the danger.

164. Because Medtronic Defendants failed to comply with their duty under federal law, they breached their “duty to use reasonable care” under Ohio law to disclose material risks of the SynchroMed® II Device to the FDA and the public, including Mrs. Carter. This duty parallels Medtronic Defendants’ requirements under federal law to timely and properly report adverse events and safety issues relating to Pump 3 through Pump 5.

165. Had the FDA been properly and timely warned of the known problems and defects associated with Mrs. Carter’s Pump 3 through Pump 5, Mrs. Carter and/or her medical providers would have learned of the dangers and heeded that warning, thereby avoiding use of Pump 3 through Pump 5.

166. As a foreseeable, direct and proximate result of the Medtronic Defendants’ failure to warn, as set forth above, about the defective condition of the SynchroMed® II Device, Mrs. Carter experienced severe pain and suffering which continues through present day and will continue into the future, a surgical procedure to completely explant her defective Pump 3

¹⁸ Id.

through Pump 5, extensive hospitalization and medical procedures, and other damages compensable by law.

167. Upon information and belief, Pump 3 through Pump 5 were defective in as much as the same did not conform to FDA approvals and requirements when the same left the control of Medtronic Defendants, contrary representations made by Medtronic Defendants.

168. With its aforesaid actions, inactions, and federal law violations, the Medtronic Defendants manifested a flagrant disregard of the safety Mrs. Carter, who might be harmed by Pump 3 through Pump 5.

169. Medtronic Defendants damaged Mrs. Carter including medical bills, lost income, permanent disfigurement, pain and suffering, and loss of consortium in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00), as will be more fully proven in the trial on the merits herein.

170. Mrs. Carter reserves the right to amend her pleadings herein or to join additional parties.

COUNT THREE (3): NEGLIGENCE

171. Mrs. Carter alleges and incorporates herein each and every allegation set forth in the preceding paragraphs as though the same were fully rewritten herein.

172. Mrs. Carter alternatively pleads a negligence claim against the Medtronic Defendants.

173. Mrs. Carter herein asserts claims under Ohio law that parallel Medtronic Defendants' duties under federal law governing Mrs. Carter's Pump 3 through Pump 5. Mrs. Carter's state law claims are based upon and arise from Medtronic Defendants' violation of and

deviation from federal regulations regarding Mrs. Carter's Pump 3 through Pump 5 as set forth herein.

174. The Medtronic Defendants, and each of them, are medical device entities engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise placing into the stream of commerce various medical devices intended for human use, including Pump 3 through Pump 5, which is a surgically implanted device that delivers medication into the intrathecal space of patients for the treatment of chronic pain, and as an alternative to oral pain medication.

175. At all times relevant hereto, the Medtronic Defendants manufactured, distributed and sold Mrs. Carter's Pump 3 through Pump 5, comprising of a pump and catheter. Mrs. Carter used Pump 3 through Pump 5 as intended by the Medtronic Defendants.

176. Under Ohio law, every manufacturer, including Medtronic Defendants has a duty to use reasonable care to avoid foreseeable dangers in their products. Specifically, the Medtronic Defendants at all relevant times hereto had a duty to use reasonable care in the manufacturer, testing, monitoring, inspection, assembly, and sale of Mrs. Carter's Pump 3 through Pump 5. Such duties are parallel to those imposed under federal law.

177. Federal law imposes post-market requirement on the Medtronic Defendants, including those found under 21 C.F.R. §820, *et seq.*, which promulgates Current Good Manufacturing Practices (CGMPs). The quality control requirements of the CGMPs are designed to ensure Medtronic Defendants' products conform to manufacturing specifications, that non-conforming products do not reach the market, and that problems with products in the

field are properly monitored, tracked and reported. The CGMPs require the Medtronic Defendants to evaluate signals of unexpected or serious events of injury in the field and report to the FDA when a device causes, or is suspected to cause, injury in the field. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of this requirement is deemed to be adulterated. 21 C.F.R. §351 (h). A manufacturer is prohibited from introducing, delivering, or selling an adulterated device into interstate commerce. 21 C.F.R. §331(a),(k).

178. As a result of numerous FDA inspections from 2006-2013 to the Medtronic Defendants' manufacturing plants in Minneapolis, Minnesota and Juncos Puerto Rico, as alleged herein, the FDA determined the SynchroMed® II Device was "adulterated" and "misbranded" and thereby violated specific CGMPs as outlined *supra* in paragraphs herein.

179. The Medtronic Defendants violated their duties to comply with their obligations to manufacture their SynchroMed® II Device in conformity with CGMPs and therefore could not ensure the safety and effectiveness of the SynchroMed® II Device received by Mrs. Carter.

180. As a foreseeable, direct and proximate result of the Medtronic Defendants' failure to use due care to avoid foreseeable dangers in their SynchroMed® II Device, Mrs. Carter's Pump 3 through Pump 5 was manufactured out of specification and were misbranded and adulterated in violation of federal law.

181. As a further foreseeable, direct and proximate result of the Medtronic Defendants' failure to use due care to avoid foreseeable dangers in their SynchroMed® II Device, Mrs. Carter's nonconforming Pump 3 through Pump 5 failed to deliver medication into

her intrathecal space at the programmed rate, causing severe pain and suffering, extensive hospitalization and medical procedures, and other damages compensable by law.

182. The damages Mrs. Carter sustained in the failure of Pump 3 through Pump 5 are the direct and proximate result of the Medtronic Defendants' actions or omissions.

183. The Medtronic Defendants' actions or omissions with regard to Pump 3 through Pump 5 show a conscious disregard for the rights and safety of Mrs. Carter which action had a great probability of causing substantial harm to Mrs. Carter, including medical bills, lost income, permanent disfigurement, pain and suffering, and loss of consortium.

184. Due to Pump 3 through Pump 5, Mrs. Carter incurred medical bills, lost income, experienced permanent disfigurement, experienced pain and suffering, and lost consortium with her loved ones and family.

185. The Medtronic Defendants' negligence damaged Mrs. Carter in excess of Seventy-Five Thousand Dollars (\$75,000.00), as will be more fully proven in the trial on the merits herein.

186. Mrs. Carter reserves the right to amend her pleadings herein or to join additional parties.

COUNT FOUR (4): NEGLIGENCE PER SE

187. Mrs. Carter alleges and incorporates herein each and every allegation set forth in the preceding paragraphs as though the same were fully rewritten herein.

188. Mrs. Carter alternatively pleads a negligence per se claim against the Medtronic Defendants.

189. Mrs. Carter herein asserts claims under Ohio law that parallel Medtronic Defendants' duties under federal law governing Mrs. Carter's Pump 3 through Pump 5. Mrs. Carter's state law claims are based upon and arise from Medtronic Defendants' violation of and deviation from federal regulations regarding Mrs. Carter's Pump 3 through Pump 5 as set forth herein.

190. The Medtronic Defendants, and each of them, are medical device entities engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise placing into the stream of commerce various medical devices intended for human use, including the SynchroMed® II Device, which is a surgically implanted device that delivers medication into the intrathecal space of patients for the treatment of chronic pain, and as an alternative to oral pain medication.

191. At all times relevant hereto, the Medtronic Defendants manufactured, distributed and sold Mrs. Carter's Pump 3 through Pump 5, comprising of a pump and catheter. Mrs. Carter used her SynchroMed® II Device as intended by the Medtronic Defendants.

192. Under Ohio law, every manufacturer, including Medtronic Defendants has a duty to use reasonable care to avoid foreseeable dangers in their products. Specifically, the Medtronic Defendants at all relevant times hereto had a duty to use reasonable care in the manufacturer, testing, monitoring, inspection, assembly, and sale of Mrs. Carter's Pump 3 through Pump 5. Such duties are parallel to those imposed under federal law.

193. Federal law imposes post-market requirement on the Medtronic Defendants, including those found under 21 C.F.R. §820, *et seq.*, which promulgates Current Good

Manufacturing Practices (CGMPs). The quality control requirements of the CGMPs are designed to ensure Medtronic Defendants' products conform to manufacturing specifications, that non-conforming products do not reach the market, and that problems with products in the field are properly monitored, tracked and reported. The CGMPs require the Medtronic Defendants to evaluate signals of unexpected or serious events of injury in the field and report to the FDA when a device causes, or is suspected to cause, injury in the field. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of this requirement is deemed to be adulterated. 21 C.F.R. §351 (h). A manufacturer is prohibited from introducing, delivering, or selling an adulterated device into interstate commerce. 21 C.F.R. §331(a),(k).

194. As a result of numerous FDA inspections from 2006-2013 to the Medtronic Defendants' manufacturing plants in Minneapolis, Minnesota and Juncos Puerto Rico, as alleged herein, the FDA determined the SynchroMed® II Device was "adulterated" and "misbranded" and thereby violated specific CGMPs as outlined *supra* in paragraphs herein.

195. The Medtronic Defendants violated their duties to comply with their obligations to manufacture their SynchroMed® II Device in conformity with CGMPs and therefore could not ensure the safety and effectiveness of the SynchroMed® II Device received by Mrs. Carter.

196. As a foreseeable, direct and proximate result of the Medtronic Defendants' failure to use due care to avoid foreseeable dangers in their SynchroMed® II Device, Mrs. Carter's Pump 3 through Pump 5 was manufactured out of specification and was misbranded and adulterated in violation of federal law.

197. As a further foreseeable, direct and proximate result of the Medtronic Defendants' failure to use due care to avoid foreseeable dangers in their SynchroMed® II Device, Mrs. Carter's nonconforming Pump 3 through Pump 5 failed to deliver medication into her intrathecal space at the programmed rate, causing severe pain and suffering which continues through present day and will continue into the future, a surgical procedure to completely explant the defective SynchroMed® II Device, extensive hospitalization and medical procedures, and other damages compensable by law.

198. The damages Mrs. Carter sustained in the failure of Pump 3 through Pump 5 are the direct and proximate result of the Medtronic Defendants' actions or omissions.

199. The Medtronic Defendants' actions or omissions with regard to Pump 3 through Pump 5 show a conscious disregard for the rights and safety of Mrs. Carter which action had a great probability of causing substantial harm to Mrs. Carter, including medical bills, lost income, permanent disfigurement, pain and suffering, and loss of consortium.

200. Due to Pump 3 through Pump 5, Mrs. Carter incurred medical bills, lost income, experienced permanent disfigurement, experienced pain and suffering, and lost consortium with her loved ones and family.

201. The Medtronic Defendants' negligence damaged Mrs. Carter in excess of Seventy-Five Thousand Dollars (\$75,000.00), as will be more fully proven in the trial on the merits herein.

202. Mrs. Carter reserves the right to amend her pleadings herein or to join additional parties.

COUNT FIVE (5): BREACH OF EXPRESS WARRANTY

203. Mrs. Carter alleges and incorporates herein each and every allegation set forth in the preceding paragraphs as though the same were fully rewritten herein.

204. Mrs. Carter alternatively pleads a breach of express warranty claim against the Medtronic Defendants.

205. At all times relevant hereto, the Medtronic Defendants expressly warranted and promised by way of written literature, advertisements, and/or other documents and/or promotional materials directed to Mrs. Carter and/or her medical providers, that despite the significant cost difference in therapy, the use of an implanted SynchroMed® II Device designed to deliver medication to the was a superior and safer method than oral medication and/or alternative means of therapy.

206. Mrs. Carter and/or her medical providers received, heard, and/or read the Medtronic Defendants' express warranties that the SynchroMed® II Device conformed to FDA regulations and specifications, and was safe, effective, and fit and proper for its intended uses and foreseeable uses.

207. Based upon the Medtronic Defendants' representations of the significant benefits of the SynchroMed® II Device as compared to other forms of pain medication delivery, Mrs. Carter purchased and underwent surgery for implantation of Pump 3 through Pump 5.

208. Mrs. Carter and/or her medical providers received, heard, and/or read the Medtronic Defendants' express warranties that Pump 3 through Pump 5 conformed to FDA regulations and specifications, and was safe, effective, and fit and proper for its intended uses and foreseeable uses.

209. Mrs. Carter and/or her medical providers relied upon the Medtronic Defendants' express warranties that Pump 3 through Pump 5 conformed to FDA regulations and specifications, and was safe, effective, and fit and proper for its intended uses and foreseeable uses, when in fact it was manufactured in violation of federal regulations and specifications and was unsafe and unfit for such uses.

210. The Medtronic Defendants breached their express warranties because the warranty and representations were untrue in that: a. The FDA had determined that the Medtronic Defendants SynchroMed® II Device implanted in Mrs. Carter was manufactured in violation of federal regulations and specifications, including CGMPs; b. The FDA violations of CGMPs committed by Medtronic Defendants meant that Medtronic Defendants was unable to confirm that the SynchroMed® II Device implanted in Mrs. Carter was safe and effective, fully conformed to specifications, and was free of defects that could lead to malfunctions having the potential to cause or contribute to serious bodily injury; and c. The FDA had determined that the SynchroMed® II Device implanted in Mrs. Carter was manufactured at a time when SynchroMed® II Devices were labeled "adulterated" and "misbranded."

211. The implanted SynchroMed® II Device's intrathecal infusion delivery of pain medication is not a superior method to oral pain medication or alternative therapy.

212. As a result of the aforementioned breach of their express warranties by Medtronic Defendants, Mrs. Carter experienced severe pain and suffering which continues through present day and will continue into the future, a surgical procedure to explant her defective Pump 3 through Pump 5, extensive hospitalization and medical procedures, and other damages compensable by law.

213. The damages Mrs. Carter sustained in the failure of Pump 3 through Pump 5 are the direct and proximate result of the Medtronic Defendants' actions or omissions.

214. The Medtronic Defendants' actions or omissions with regard to Pump 3 through Pump 5 show a conscious disregard for the rights and safety of Mrs. Carter which action had a great probability of causing substantial harm to Mrs. Carter, including medical bills, lost income, permanent disfigurement, pain and suffering, and loss of consortium.

215. Due to Pump 3 through Pump 5, Mrs. Carter incurred medical bills, lost income, experienced permanent disfigurement, experienced pain and suffering, and lost consortium with her loved ones and family.

216. The Medtronic Defendants' negligence per se damaged Mrs. Carter in excess of Seventy-Five Thousand Dollars (\$75,000.00), as will be more fully proven in the trial on the merits herein.

217. Mrs. Carter reserves the right to amend her pleadings herein or to join additional parties.

COUNT FIVE (5): SPOILATION OF EVIDENCE

218. Mrs. Carter alleges and incorporates herein each and every allegation set forth in the preceding paragraphs as though the same were fully rewritten herein.

219. Mrs. Carter herein asserts claims under Ohio law that parallel Medtronic Defendants' duties under federal law governing Mrs. Carter's Pump 3 through Pump 5. Mrs. Carter's state law claims are based upon and arise from Medtronic Defendants' violation of and deviation from federal regulations regarding Mrs. Carter's Pump 3 through Pump 5 as set forth herein.

220. The Medtronic Defendants, and each of them, are medical device entities engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise placing into the stream of commerce various medical devices intended for human use, including the SynchroMed® II Device, which is a surgically implanted device that delivers medication into the intrathecal space of patients for the treatment of chronic pain, and as an alternative to oral pain medication.

221. At all times relevant hereto, the Medtronic Defendants manufactured, distributed and sold Mrs. Carter's Pump 3 through Pump 5, comprising of a pump and catheter. Mrs. Carter used her Mrs. Carter's Pump 3 through Pump 5 as intended by the Medtronic Defendants.

222. Under Ohio law, every manufacturer, including the Medtronic Defendants have a duty to use reasonable care to avoid foreseeable dangers in their products. Specifically, the Medtronic Defendants at all relevant times hereto had a duty to use reasonable care in the manufacturer, testing, monitoring, inspection, assembly, and sale of Mrs. Carter's Pump 3 through Pump 5. Such duties are parallel to those imposed under federal law.

223. Federal law imposes post-market requirement on the Medtronic Defendants, including those found under 21 C.F.R. §820, *et seq.*, which promulgates Current Good Manufacturing Practices (CGMPs). The quality control requirements of the CGMPs are designed to ensure Medtronic Defendants' products conform to manufacturing specifications, that non-conforming products do not reach the market, and that problems with products in the field are properly monitored, tracked and reported. The CGMPs require the Medtronic

Defendants to evaluate signals of unexpected or serious events of injury in the field and report to the FDA when a device causes, or is suspected to cause, injury in the field. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of this requirement is deemed to be adulterated. 21 C.F.R. §351 (h). A manufacturer is prohibited from introducing, delivering, or selling an adulterated device into interstate commerce. 21 C.F.R. §331(a),(k).

224. The Medtronic Defendants knew or should have known of the pending or probable litigation with Mrs. Carter regarding Mrs. Carter's Pump 3 through Pump 5.

225. Upon information and belief, Mrs. Carter's Pump 3 through Pump 4 were delivered to the Medtronic Defendants without Mrs. Carter's consent and were not preserved for the instant litigation.

226. Upon information and belief, Mrs. Carter's Pump 3 through Pump 4 were not preserved by the Medtronic Defendants.

227. The Medtronic Defendants' spoliation of evidence disrupted and/or will disrupt Mrs. Carter's case.

228. The Medtronic Defendants acted with actual malice towards Mrs. Carter.

229. The Medtronic Defendants acted with a conscious disregard for the safety of Mrs. Carter where there was significant risk of substantial harm to Mrs. Carter.

230. As a further direct and proximate result of the Medtronic Defendants' evidentiary actions or omissions, Mrs. Carter incurred hospital, medical, and other related expenses, and will continue to incur the same in the future due to the permanent nature of her injuries.

231. The Medtronic Defendants' spoliation of evidence damaged Mrs. Carter in excess of Seventy-Five Thousand Dollars (\$75,000.00), as will be more fully proven in the trial on the merits herein.

232. Mrs. Carter reserves the right to amend her pleadings herein or to join additional parties.

WHEREFORE, Mrs. Carter prays this Honorable Court will grant her judgment as follows:

A. A joint and several judgment against the Medtronic Defendants in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00), for compensatory and punitive damages, statutory damages, plus interest including pre-judgment and post judgment interest, costs, and attorneys' fees; and

B. For any and all other relief to which Mrs. Carter may be entitled, as a matter of law and/or equity.

Respectfully submitted,

THERAN SELPH & ASSOCIATES, LTD.

/s/ Theran J. Selph, Sr.

Theran J. Selph, Sr. (0079376)

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Counsel for Plaintiff Carolyn R. Carter

JURY DEMAND

Pursuant to Federal Rules of Civil Procedure, Mrs. Carter hereby request a trial by jury of eight (8) persons on all issues triable by a jury.

/s/ Theran J. Selph, Sr.

Theran J. Selph, Sr. (0079376)

Counsel for Plaintiff Carolyn R. Carter

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